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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,438	02/11/1999	MURRAY C. MAYTOM	PC10015AJTJ	8766

7590

04/26/2004

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/248,438

Applicant(s)

MAYTOM ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 21&22.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 2, 2004 has been entered.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 2, 5-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,469,012, in view of Courtois et al., Tay et al, Beretta et al, and Chancellor et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the U.S. patent No. 6,469,012, similar to the instant claims, are drawn to methods of treating sexual dysfunction broadly and male erectile dysfunction.

U.S. Patent No. 6,469,012 does not expressly claim the treated subject is with injured spinal cord.

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1. However, Courtois et al. teaches that there are two pathways of erectile functions: Sacral pathway responsible for reflexogenic erection, and thoracic-lumbar pathway responsible for psychogenic erection, and spinal cord injury does not block all the pathways. See, particularly, pages 629-631. Tay et al. teaches that erectile dysfunction caused by injured spinal cord may be psychogenic, not organic. See the abstract. Berretta et al. and Chancellor et al. teach that vasoactive compounds are known to be useful for treatment of erectile dysfunction in men with injured spinal cord. See the abstracts.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury, including those who exhibits essentially no residual erectile function.

2. A person of ordinary skill in the art would have been motivated to employ the vasoactive, compounds herein for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function because the general established mechanism of sildenafil indicates it will be useful for treatment of ED in men with proper corpus cavernosum tissue, including those with injured spinal cord. A person of ordinary skill in the art would have reasonable expected that sildenafil would be useful for treatment of ED in men including those exhibits essentially no residual erectile function, particularly in view of the fact that not all spinal cord injuries cause erectile dysfunction and not all the erectile dysfunction caused by spinal cord injury are organic. Further, a person of ordinary skill in the art would have been motivated to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury because vasoactive compounds useful for treating erectile dysfunction are known to be useful for

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treating erectile dysfunction caused by spinal cord injury. Finally, an agent known to be useful for treating erectile dysfunction caused by spinal cord injury in men would have reasonably expected to be useful for treating erectile dysfunction caused by spinal cord injury in any men, including those who exhibit essentially no residue erectile function.

Claim Rejection 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/28902 (of record) in view of Courtois et al., Tay et al., Beretta et al., and Chancellor et al.

WO 94/28902 teaches that the compounds of the claims are vasoactive compounds, known to be useful in the treatment of male erectile, sexual dysfunction. The administration may be oral. See, e.g., the abstract, page 2, and the claims. More specifically, sildenafil selectively inhibits PDEv enzyme and lead to an elevation of cGMP levels in corpus cavernosum tissue. The elevation of cGMP levels in corpus cavernosum tissue cause the tissue relaxation and consequent penile erection. See, page 9, the last paragraph bridging to page 10 in WO 94/28902.

5. WO 94/28902 does not teach expressly the employment of the treatment for man with injured spinal cord.

6. However, Courtois et al. teaches that there are two pathways of erectile functions: Sacral pathway responsible for reflexogenic erection, and thoracic-lumbar pathway responsible for psychogenic erection, and spinal cord injury does not block all the pathways. See, particularly,

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pages 629-631. Tay et al. teaches that erectile dysfunction caused by injured spinal cord may be psychogenic, not organic. See the abstract. Berretta et al. and Chancellor et al. teach that vasoactive compounds are known to be useful for treatment of erectile dysfunction in men with injured spinal cord. See the abstracts.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury, including those who exhibits essentially no residual erectile function.

7. A person of ordinary skill in the art would have been motivated to employ the vasoactive, compounds herein for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function because the general established mechanism of sildenafil indicates it will be useful for treatment of ED in men with proper corpus cavernosum tissue, including those with injured spinal cord. A person of ordinary skill in the art would have reasonable expected that sildenafil would be useful for treatment of ED in men including those exhibits essentially no residual erectile function, particularly in view of the fact that not all spinal cord injuries cause erectile dysfunction and not all the erectile dysfunction caused by spinal cord injury are organic. Further, a person of ordinary skill in the art would have been motivated to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury because vasoactive compounds useful for treating erectile dysfunction are known to be useful for treating erectile dysfunction caused by spinal cord injury. Finally, an agent known to be useful for treating erectile dysfunction caused by spinal cord injury in men would have reasonably

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expected to be useful for treating erectile dysfunction caused by spinal cord injury in any men, including those who exhibit essentially no residue erectile function.

Response to the Arguments

Applicants' amendments and remarks submitted January 2, 2004 have been fully considered, but are not persuasive.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the primary reference teaches the genus (treating man), the instant application is directed to subgenus (spinal cord injured man). The secondary references shows that: a) there is no substantially difference between treating spinal cord injured man and man in general (both known to be treated with vasoactive compounds); b) the underline mechanism for treating erectile dysfunctions by the compounds herein (vasoactivation) has nothing to do with the erection pathways which may be interrupted by spinal cord injury; c) spinal cord injury does not block all of the erection pathways. Therefore, one of ordinary skill in the art would have understand that the method as disclosed in the primary reference would be useful for any man with proper corpus cavernosum tissue.

9. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on


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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Taken the cited references as a whole, the claimed method would have been obvious as discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

April 21, 2004